

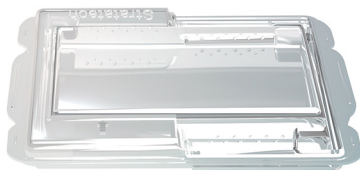


StrataGraft® is an off-white, rectangular sheet consisting of a viable, bioengineered, allogeneic cellularized scaffold product derived from keratinocytes grown on gelled collagen containing dermal fibroblasts.

Each cryopreserved StrataGraft construct must be prepared for use with 1 bottle of Hold Solution and 1 Hold Dish. The Hold Solution is a cell-culture medium that is not supplemented with growth factors.

	StrataGraft	Hold Solution	Hold Dish
			
	NDC: 73612-200-01	Part number: SPC-IP-0781	Part number: SPC-RM-0122
Dimensions	Carton: 10.375" × 6.875" × 0.8125"	Bottle: 1.2" × 1.5" Carton (n=3): 8.031" × 6.719" × 2.75"	Clear pouch: 10" × 6.625" × 0.75" Carton (n=3): 8.031" × 6.719" × 2.75"
How supplied	An approximately 100 cm ² rectangular sheet (approximately 8 cm × 12.5 cm), loosely adherent to a polycarbonate membrane within a polystyrene Insert Tray frame, packaged in a sealed foil pouch contained within a carton, and shipped on dry ice	Provided in a plastic bottle contained within a laminated foil pouch that is packaged 3 per carton and shipped separately at ambient temperature	Contained in a clear pouch that is packaged 3 per carton and shipped separately at ambient temperature
Storage and handling	Store between -70°C and -90°C (-94°F to -130°F)	Store between 2°C and 8°C (36°F and 46°F)	Store at ambient temperature
Dispose of unused StrataGraft and materials that have come into contact with StrataGraft as surgical biohazardous waste in accordance with local requirements. Call 1-877-647-2239 for further instructions.			
Shelf life	18 months	12 months	42 months from date of irradiation processing
Please refer to the product packaging for the expiration date.			
Special handling instructions	StrataGraft must be maintained in a freezer at -70°C to -90°C or on dry ice during transport, storage, and transfer to the operating room until initiation of the thaw process, and it cannot be refrozen once thawed.		
Ordering	<ul style="list-style-type: none"> All orders will be fulfilled via direct distribution by Mallinckrodt To safeguard against accidental mishandling, it is necessary to order extra Hold Solution and Hold Dishes. Please note these materials are shipped in quantities of 3 Example for ordering additional quantities: <ul style="list-style-type: none"> 1 sheet must order (1) 3-pack of Hold Solution and (1) 3-pack of Hold Dishes 2 sheets must order (1) 3-pack of Hold Solution and (1) 3-pack of Hold Dishes 3 sheets must order (2) 3-packs of Hold Solution and (2) 3-packs of Hold Dishes Call 1-877-647-2239 for purchase order and invoice tracking.		
Product returns	Subject to the current Return Goods Policy in effect at the time of return. Contact StrataGraft support at 1-877-647-2239 with any questions.		

INDICATION

StrataGraft® is an allogeneic cellularized scaffold product indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with known allergies to murine collagen or products containing ingredients of bovine or porcine origin.



For more information, visit [StrataGraft.com](https://www.StrataGraft.com) or call 1-877-647-2239 for additional support

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- StrataGraft contains glycerin. Avoid glycerin in patients with known sensitivity (irritant reaction) to glycerin.
- Severe hypersensitivity reactions may occur. Monitor for both early and late symptoms and signs of hypersensitivity reaction following StrataGraft application, and treat according to standard medical practice.
- StrataGraft contains cells from human donors and may transmit infectious diseases or infectious agents, eg, viruses, bacteria, or other pathogens, including the agent that causes transmissible spongiform encephalopathy (TSE, also known as Creutzfeldt-Jakob disease [CJD or variant CJD]).

StrataGraft is a xenotransplantation product because of an historic exposure of the keratinocyte cells to well-characterized mouse cells. The cell banks have been tested and found to be free of detectable adventitious agents, and mouse cells are not used in the manufacture of StrataGraft; however, these measures do not entirely eliminate the risk of transmitting infectious diseases and disease agents.

Transmission of infectious diseases or agents by StrataGraft has not been reported.

- Because StrataGraft is a xenotransplantation product, StrataGraft recipients should not donate whole blood, blood components, plasma, leukocytes, tissues, breast milk, ova, sperm, or other body parts for use in humans.

Adverse Reactions

- The most common adverse reactions (incidence $\geq 2\%$) were itching (pruritus), blisters, hypertrophic scar, and impaired healing. Other adverse events reported are included in the full Prescribing Information.

Pediatric Use

- The safety and effectiveness of StrataGraft in pediatric patients (<18 years) have not been established.

Please see additional Important Safety Information on previous page and full [Prescribing Information](#).

Reference: 1. StrataGraft. Package insert. Stratatech Corporation; 2021.